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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,687	04/26/2005	Wing Sum Cheung	4280.72689	8727

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EXAMINER	
DAVIS, RUTH A	

ART UNIT	PAPER NUMBER
1651	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/532,687	CHEUNG, WING SUM	
	Examiner	Art Unit	
	Ruth A. Davis	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 November 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12,14 and 15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12,14-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment and response filed on November 16, 2007 have been received and entered into the case. Claims 1 – 12 and 14 – 15 are pending and have been considered on the merits. All arguments have been fully considered.

Specification

Specification objections are withdrawn due to the response filed on November 16, 2007.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1 – 12 and 14 – 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a rabbit skin wherein the skin is processed by eluting and fractioning based on molecular weight. However, the specification as originally filed does not describe such a process. Thus the limitations contain new matter.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1 – 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 and its dependents are drawn to a composition, however are rendered vague and indefinite for reciting "a rabbit having rabbit skin" because it is unclear if applicant is intending to claim a rabbit, or a rabbit skin. As claimed, the independent claim is drawn to a rabbit and the dependent claims are drawn to a rabbit skin.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1 – 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Shibayama et al. (US 5057324).

Applicant claims a rabbit skin containing kallikrein production inhibition activity wherein the skin is obtained by vaccinating rabbit skin tissues with vaccinia virus, feeding the rabbit, killing the rabbit when the skin tissues are inflamed, skinning the rabbit; and eluting a portion

and fractionating based on molecular weight. The virus is Lister strain, Ikeda strain, Dairen strain, EM-63 starin; the vaccinating is effected b injecting 0.1 – 0.4 ml solution containing 10^6 – 10^9 virus/ml each site, 100 – 250 cites per rabbit weighing 1.5 – 3Kg. The rabbit is a Japanese white, New Zealand white, Chinese or Blue-violet rabbit. The skin is inflamed when visible blains are present, the skin is red to mauve and thick, and the subcuticle hip is swollen; the skin possesses 0.5 iu/g SART activity.

Shibayama teaches a rabbit skin extract that has inhibitory activity against kallikrein formation, wherein the substance is useful as a drug (abstract). The substance is obtained by infecting a rabbit skin with vaccinia virus (col.1 line 45-65) and removing the skin (example 1). Shibayama teaches the extract in a drug composition with a pharmaceutically acceptable carrier (claims).

Although the reference does not expressly teach all of the limitations regarding how the rabbit skin is produced, these limitations are considered to be product by process type limitations. The patentability of a product does not depend on its method of production. If the claimed product is the same or obvious from a product in the prior art (i.e. the product disclosed in the cited reference), the claim is unpatentable even though the reference product was made by a different process. When the prior art discloses a product which reasonably appears to be identical with or slightly different than the claimed product-by-process, rejections under 35 U.S.C 102 and/or 35 U.S.C 103 are proper. (MPEP 2113)

Therefore, the reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1 – 12 and 14 – 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shibayama et al. (US 5057324).

Applicant claims a rabbit skin containing kallikrein production inhibition activity wherein the skin is obtained by vaccinating rabbit skin tissues with vaccinia virus, feeding the rabbit, killing the rabbit when the skin tissues are inflamed, skinning the rabbit, and eluting and fractionating a portion based on molecular weight. The virus is Lister strain, Ikeda strain, Dairen strain, EM-63 starin; the vaccinating is effected b injecting 0.1 – 0.4 ml solution containing 10^6 – 10^9 virus/ml each site, 100 – 250 cites per rabbit weighing 1.5 – 3Kg. The rabbit is a Japanese white, New Zealand white, Chinese or Blue-violet rabbit. The skin is inflamed when visible blains are present, the skin is red to mauve and thick, and the subcuticle hip is swollen; the skin possesses 0.5 iu/g SART activity. Applicant additionally claims a drug and health food comprising water and an extract of the rabbit skin, wherein the extract is made by a particular process.

Shibayama teaches a rabbit skin extract that has inhibitory activity against kallikrein formation, wherein the substance is useful as a drug (abstract). The substance is obtained by

infecting a rabbit skin with vaccinia virus (col.1 line 45-65). Shibayama teaches the extract in a drug composition with a pharmaceutically acceptable carrier (claims).

Although the reference does not expressly teach all of the limitations regarding how the rabbit skin is produced, these limitations are considered to be product by process type limitations. The patentability of a product does not depend on its method of production. If the claimed product is the same or obvious from a product in the prior art (i.e. the product disclosed in the cited reference), the claim is unpatentable even though the reference product was made by a different process. When the prior art discloses a product which reasonably appears to be identical with or slightly different than the claimed product-by-process, rejections under 35 U.S.C 102 and/or 35 U.S.C 103 are proper. (MPEP 2113)

The reference does not teach feeding the rabbit. However as a matter of standard protocol, animals used in laboratory experiments are required to be treated humanely which includes feeding of the animals. Thus, while the reference does not expressly state the rabbits were fed, it would have been a matter of standard procedure to do so, and thus obvious to one of ordinary skill in the art.

The reference does not teach each of the claimed strains of vaccinia, types of rabbit, wherein the inflammation reaches the claimed point, or SART activity of the skin. However, at the time of the claimed invention, each of the claimed strains and rabbits were well known and used in the art for animal and laboratory experiments. Thus, it would have been within the purview of one in the art to use any of the instant strains or rabbits as a matter of routine practice. Regarding the SART activity, the skin of the art is the same as that claimed, thus it must intrinsically exhibit the claimed activity.

The reference does not teach the amount of virus injected into the rabbit. However, at the time of the claimed invention, it would have been well within the purview of one of ordinary skill in the art to optimize such injections as a matter of routine experimentation. Thus, one of ordinary skill in the art would have been motivated by routine practice to optimize the amount of virus injected into the rabbit with a reasonable expectation for successfully obtaining an effective extract against the formation of kallikrein.

The reference does not teach water as the pharmaceutically acceptable carrier. However, at the time of the claimed invention, water was a well known and recognized carrier. Thus it would have been obvious to one of ordinary skill in the art to combine the extract with water in following the teachings of Shibayama.

Response to Arguments

Applicant argues that the references do not teach the selection of vaccina virus claimed; that the instant composition provides for more choices of virus; that the claimed rabbit varieties are not disclosed; and that the reference does not teach the claimed method for making the extract. Applicant additionally argues that the reference teaches away from the claimed invention in column 4, where it discloses other fractions which do not show activity.

However, these arguments fail to persuade because as stated in the above rejections, the reference clearly teaches vaccina viruses as in claim 1. Thus, while the reference may not disclose each of the claimed strains and species of rabbit, the reference clearly teaches the vaccine virus in rabbits to obtain effective extracts. Further, these additional strains and varieties

are interpreted as product by process type limitations. Moreover, the particular strain or variety of rabbit do not appear to materially change the effective rabbit extract disclosed. Regarding the method for making the extract, it is noted that Shibayama teaches washing with solvents and separation by molecular weight, which is a similar process as claimed and results in an extract with the same properties. It is reiterated that the limitations to making the extract are interpreted as product by process limitations, which do no appear to materially effect the resulting extract. Finally, regarding the alleged teachings away, it is acknowledged that the reference teaches some fractions do not exhibit activity, however it is clear in the examples (example 1, col.3) that active fractions are obtained. Thus the reference clearly teaches active extracts as claimed.

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 571-272-0915. The examiner can normally be reached on M-F 7:00 -3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ruth A. Davis/
Primary Examiner
Art Unit 1651

January 31, 2008